

**REMARKS**

**Summary of Office Action**

Claims 46-48, 50-61, 64-74, 76 and 77 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO/2003/039505, cited in the instant Office Action as the alleged English equivalent, Bankowski et al., U.S. Patent No. 7,294,330 (hereafter "BANKOWSKI").

Claims 62 and 63 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of Gers-Barlag et al., US Patent Publication 2002/0077372 (hereafter "GERS").

Claims 46-48, 50-56, 64-70, 72-74, 76 and 77 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shen, U.S. Patent No. 6,042,816 (hereafter "SHEN"), in view of Yu et al., U.S. Patent No. 5,571,841 (hereafter "YU").

Claims 57-63 and 71 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS.

**Response to Office Action**

Reconsideration and withdrawal of the rejections of record are again respectfully requested, in view of the following remarks.

***Response to Rejections of Claims under 35 U.S.C. § 103(a) over BANKOWSKI as Primary Document***

Claims 46-48, 50-61, 64-74, 76 and 77 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI, and claims 62 and 63 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over BANKOWSKI in view of GERS. The rejections repeat

the allegations set forth in the previous Office Action and essentially allege that with the exception of claims 62 and 63 the elements of the rejected claims are either disclosed or rendered obvious by BANKOWSKI and that the elements recited in claims 62 and 63 are rendered obvious by GERS. The Examiner again concedes that BANKOWSKI fails to disclose “an example wherein the claimed components, at the claimed percentages are combined into a single composition” but alleges that BANKOWSKI teaches “that all of the claimed components may be combined into a composition within the claimed percentage ranges”.

Applicants respectfully traverse these rejections for all of the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein.

It is pointed out again that BANKOWSKI teaches hundreds, if not thousands, of substances which are suitable as  $\beta$ -glucuronidase-inhibiting substances. Further, even the specific class of compounds that is mentioned as one of many examples of suitable (and structurally most diverse)  $\beta$ -glucuronidase-inhibiting substances and includes mandelic acid, i.e., aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group, includes a total of 13 specific acids, i.e., mandelic acid, para-hydroxymandelic acid, rosemary acid, ferulic acid, chlorogenic acid, salicylic acid, 2,3-dihydroxybenzoic acid (pyrocatechic acid), 2,4-dihydroxybenzoic acid ( $\beta$ -resorcylic acid), 2,5-dihydroxybenzoic acid (gentisic acid), 2,6-dihydroxybenzoic acid ( $\gamma$ -resorcylic acid), 3,4-dihydroxybenzoic acid (protocatechuic acid), 3,5-dihydroxybenzoic acid ( $\alpha$ -resorcylic acid), and gallic acid and a total of 12 different esters of these acids (the methyl, ethyl, isopropyl, propyl, butyl, hexyl, ethylhexyl, octyl, decyl, ethyloctyl, cetyl and stearyl esters) and a total of three different alkali metal salts of these acids (if the Sr and Cs salts

are disregarded), resulting in a total of  $13 \times 15 = 195$  different substances as examples of aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group and esters and salts thereof. Of these 195 compounds three compounds (less than 2 %), i.e., rosemary acid, ferulic acid and the sodium salt of para-hydroxymandelic acid, are mentioned as particularly preferred.

In view of the foregoing facts and additionally taking into account that antiperspirant active compounds are only one of the host of examples of non-essential components that can be present in the compositions of BANKOWSKI and that activated aluminum compounds in turn are only one of several examples of antiperspirant active compounds that may be used according to BANKOWSKI, Applicants are still unable to agree with the Examiner that BANKOWSKI teaches a “reasonable number of embodiments which are only directed to deodorant and antiperspirant formulations” as asserted at page 15 of the instant Office Action.

Applicants note that at the bottom of page 15 of the instant Office Action the Examiner further alleges that BANKOWSKI “also teach[es] hydroxycarboxylic acids as the first beta-glucuronidase inhibiting substance and mandelic acid as the first aromatic carboxylic acid, as well as aluminum chlorohydrate as a preferred antiperspirant salt.”

In this regard, it is pointed out that while BANKOWSKI mentions “hydroxycarboxylic acids as the first beta-glucuronidase inhibiting substance”, the hydroxycarboxylic acids first mentioned in BANKOWSKI are not aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group but (non-aromatic) mono- $\alpha$ -hydroxycarboxylic acids having 2-6 carbon atoms (see col. 2, lines 10-11 in combination with the sentence bridging columns 2 and 3 of BANKOWSKI). In fact, aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals,

1-6 hydroxyl groups and 1 carboxyl group are mentioned in BANKOWSKI only as the sixth example of beta-glucuronidase inhibiting substances.

Also, even if mandelic acid were the first aromatic carboxylic acid mentioned in BANKOWSKI, the fact remains that rosemary acid and ferulic acid (and para-hydroxymandelic acid in the form of its sodium salt) are mentioned as preferred examples of the class of aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group (and esters and salts thereof).

It further is pointed out that the instant claims recite an antiperspirant activated aluminum compound, not just an (any) antiperspirant aluminum compound such as aluminum chlorohydrate.

Regarding the ratios (a) : (b) recited in the instant claims it is pointed out again that even based on the most preferred concentration ranges mentioned in BANKOWSKI for components corresponding to (a) and (b) the ratio (a) : (b) would be in the range of from 3,000 : 1 to 5 : 1. Further, there is no indication whatsoever in BANKOWSKI that the ratio (a) : (b) is a result-effective variable, wherefore it is not seen that one of ordinary skill in the art would have any reason to try to find optimum ratios within (let alone outside) this extremely broad range.

It also has to be taken into account here that the only exemplified compositions of BANKOWSKI which contain aluminum chlorohydrate (not indicated to be activated) and an aromatic carboxylic acid having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group (all different from mandelic acid) show ratios corresponding to (a) : (b) as recited in the instant claims of 800:1, about 40:1 and 50:1, respectively, i.e. far outside the ranges recited in the instant claims (by a factor of at least 2.7).

In this regard it further is noted that the exemplified compositions of BANKOWSKI which contain aluminum chlorohydrate and an aromatic carboxylic acid having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group (all different from mandelic acid) are the only real guidance provided by BANKOWSKI for one of ordinary skill in the art with respect to the ratio of (a) : (b) because even the most preferred concentration ranges indicated by BANKOWSKI for the corresponding classes of compounds leave it completely open which additional components are to be present in a corresponding composition. By way of example, it is apparent that the most preferred concentration range for aromatic carboxylic acids having 6-20 carbon atoms, 1-2 phenyl radicals, 1-6 hydroxyl groups and 1 carboxyl group (and esters and salts thereof) indicated by BANKOWSKI applies to not only compositions which additionally contain an antiperspirant (and in particular, an (activated) aluminum compound), but also to, for example, compositions which contain no antiperspirant at all but instead contain, e.g., several of the other substances which may optionally be present in a composition that is encompassed by the disclosure of BANKOWSKI (corresponding compositions are exemplified by BANKOWSKI).

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions, the instant rejection under 35 U.S.C. § 103(a) over BANKOWSKI and the rejection under 35 U.S.C. § 103(a) over BANKOWSKI and GERS are without merit, wherefore withdrawal thereof is again respectfully requested.

***Response to Rejections of Claims under 35 U.S.C. § 103(a) over SHEN as Primary Document***

Claims 46-48, 50-56, 64-70, 72-74, 76 and 77 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU and claims 57-63 and 71 remain rejected

under 35 U.S.C. § 103(a) as allegedly being unpatentable over SHEN in view of YU in further view of GERS. The rejections essentially repeat the allegations set forth in the previous Office Actions and assert, *inter alia*, that SHEN teaches compositions comprising enhanced antiperspirant salts, which allegedly reads on activated antiperspirants, alpha-hydroxycarboxylic acids, and water. The Examiner concedes that SHEN does not teach mandelic acid as hydroxycarboxylic acid but alleges that YU cures this deficiency of SHEN. In this regard, the rejection essentially asserts that YU would have rendered it obvious to one of ordinary skill in the art to produce the formulations of SHEN with mandelic acid as hydroxycarboxylic acid. One of ordinary skill in the art would allegedly have been motivated to do so “because [SHEN] teaches antiperspirant compositions comprising hydroxycarboxylic acids and [YU] teach[es] that alpha-hydroxycarboxylic acids, such as mandelic acid, may be added to antiperspirant formulations to increase efficacy and to reduce wrinkles”. Page 10, second paragraph of instant Office Action.

Applicants respectfully traverse these rejections for all of the reasons which are set forth in the responses to the previous Office Actions. The corresponding remarks are expressly incorporated herein.

It is pointed out again that the hydroxycarboxylic acids which are to be employed according to SHEN are hydroxy substituted lower alkanolic acids (preferably alkanolic acids having from 2 to 4 carbon atoms in the alkanolic acid chain). This clearly excludes araliphatic acids such as mandelic acid (having a total of 8 carbon atoms).

Applicants note that at page 17 of the instant Office Action the Examiner alleges that “Shen et al. teach preferred acids having 2-4 carbon atoms and do not exclude or teach away from the use of acids with greater than 4 carbon atoms.”

In this regard, it is pointed out that the question here is not whether SHEN teaches away from the use of “acids with greater than 4 carbon atoms” but whether SHEN provides an apparent reason to replace any of the acids which are specifically mentioned (and recommended) by SHEN by an acid which is not even mentioned (let alone recommended) by SHEN, i.e., mandelic acid.

Applicants submit that the only acids which are mentioned in col. 6, lines 45-62 of SHEN as being suitable for use in the compositions taught therein are amino- and/or hydroxy-substituted lower alkanolic acids (including substituted derivatives thereof). SHEN also teaches that the lower alkanolic acids “will generally have 2 to 6, preferably 2 to 4, carbon atoms in the alkanolic acid chain”. In contrast, mandelic acid is neither an alkanolic acid nor does it satisfy the requirement regarding the number of carbon atoms (mandelic acid has 8 carbon atoms). Neither does mandelic acid bear any structural resemblance to the acids which are preferred according to SHEN, i.e., glycine, alanine, and glycolic acid (aliphatic acids having (merely) 2 or 3 carbon atoms).

Applicants note that at page 17 of the instant Office Action the Examiner further alleges that “the teachings of YU et al. provide the motivation to add mandelic acid to the formulations of Shen and Shen provides no teaching that would lead one to believe said addition would render said formulations inoperable.”

In this regard, it is pointed out again that YU discloses hundreds, if not thousands of hydroxycarboxylic acids which are theoretically suitable for the purpose mentioned therein (enhancing the therapeutic efficacy of cosmetic or pharmaceutical agents of topically applied agents). Further, YU employs acids which are most preferred according to SHEN, i.e., glycolic acid and lactic acid, in several of the Examples thereof, whereby it is made clear to one of ordinary skill in the art that these (and similar) acids can serve the dual purpose of (i) increasing and/or stabilizing

the HPLC peak 4:3 ratio of the antiperspirant salt (SHEN) and (ii) enhancing the therapeutic efficacy of cosmetic or pharmaceutical agents of topically applied agents (YU). No such conclusion is possible for mandelic acid because SHEN does not even mention - let alone recommend - araliphatic acids (having 7 or more carbon atoms) for the purposes disclosed therein. Moreover, in contrast to acids that are specifically recommended by SHEN, mandelic acid is not employed in any of the 29 Examples of YU.

In view of the foregoing facts it is submitted that even if one were to assume, *arguendo*, that one of ordinary skill in the art would not conclude from the disclosure of SHEN that replacing the hydroxy substituted lower alkanolic acids by mandelic acid would make the invention taught therein inoperable, it cannot reasonably be denied in Applicants' opinion that YU fails to provide an apparent reason for one of ordinary skill in the art to replace the hydroxy substituted lower alkanolic acids expressly mentioned (and recommended) in SHEN by mandelic acid, at least because YU makes it clear that even for the purposes taught by YU the hydroxy substituted lower alkanolic acids which are to be employed according to SHEN are at least as suitable as mandelic acid.

It further is emphasized again that SHEN requires the use of a soluble calcium salt (see, e.g., claim 1 of SHEN) and that calcium mandelate is only slightly soluble in water, which clearly is a disincentive rather than a motivation to use mandelic acid for the purpose disclosed in SHEN and is yet another reason why one of ordinary skill in the art would not be prompted (but rather discouraged) to use mandelic acid as hydroxycarboxylic acid in the stabilization process disclosed by SHEN.

Applicants note that in this regard the Examiner takes the position that "Shen does not require a complex of said Ca and said hydroxyl acid, there is no requirement in Shen that the



inclusion of Ca ions and mandelic acid are from the addition of Ca-mandelate”. Page 17, third paragraph of the instant Office Action.

In response, it is submitted that it is irrelevant in the present context whether or not there is a “requirement” that the Ca ions and mandelic acid are from the addition of Ca-mandelate. Rather, it is apparent to one of ordinary skill in the art that adding both a water-soluble calcium salt (of any acid) and mandelic acid (which according to the Examiner would be an apparent choice for increasing and/or stabilizing the HPLC peak 4:3 ratio of the antiperspirant salt of SHEN in view of the teaching of YU) to an aqueous composition according to SHEN would inevitably result in the formation (and likely precipitation) of a Ca salt with an acid that exhibits a lower solubility than the originally employed soluble Ca salt, i.e., calcium mandelate. This has nothing to do with a “requirement” but is a law of nature (chemistry) that one of ordinary skill in the art would be aware of.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the responses to the previous Office Actions, SHIN in view of YU (and GERS) fails to render obvious the subject matter of any of the claims of record. In view thereof, withdrawal of the instant rejection under 35 U.S.C. § 103(a) over SHEN in view of YU and the rejection under 35 U.S.C. § 103(a) over SHEN in view of YU and GERS is clearly warranted as well and thus respectfully requested again.

**CONCLUSION**

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, wherefore an early issuance of the Notices of Allowance and Allowability is again respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,  
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/Heribert F. Muensterer/  
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